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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,522	02/05/2001	Maria Altamura	205 010	4796

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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 05/20/2002

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/762,522

Applicant(s)

ALTAMURA et al.

Examiner

Brenda Coleman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-15, 19, and 20 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-15, 19, and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Claims 2-15, 19 and 20 are pending in the application.

Priority

1. Any non-provisional application claiming the benefit of one or more prior filed copending nonprovisional applications or international applications designating the United States of America must contain or be amended to contain in the first sentence of the specification following the title a reference to each such prior application, identifying it by application number (consisting of the series code and serial number) or international application number and international filing date and indicating the relationship of the applications. Cross - references to other related applications may be made when appropriate.

“This application is a national stage entry under 35 U.S.C. § 371 of PCT/EP/05459, filed July 30, 1999.” is suggested.

Specification

2. 35 U.S.C. 112, first paragraph, requires the specification to be written in "full, clear, concise, and exact terms." The specification is replete with terms which are not clear, concise and exact. The specification should be revised carefully in order to comply with 35 U.S.C. 112, first paragraph. Examples of some unclear, inexact or verbose terms used in the specification are:

- a) on page 1, line 26 it is not known what is meant by “ed”;
- b) on page 1, line 30 it is not known what is meant by “naphtalene”;

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- c) on page 1, part of line 32 is covered with "AMENDED SHEET";
- d) on page 2, lines 10-12, it is not known what is meant by "piperazine possibly substituted on **one** of its nitrogen atoms";
- e) on page 3, line 9 it is not known what is meant by "monocyclic";
- f) on page 5, line 5 it is not known what is meant by "tryptophane";
- g) on page 5, line 15 it is not known what is meant by "4-tetrahydrothiopyranyl";
- h) on page 5, line 16 it is not known what is meant by "1-oxo-tetrahydrothiopyran-4-yl";
- i) on page 10, line 32 is missing part of the text because of "AMENDED SHEET";
- j) on page 12, line 31 is missing part of the text because of "AMENDED SHEET";
- k) on page 42, line 30 is missing part of the text because of "AMENDED SHEET";
and
- l) on page 43, line 31 is missing part of the text because of "AMENDED SHEET".

Applicant's cooperation is requested in correcting any other minor errors of which applicant may become aware in the specification.

Applicant's are reminded that any amendments to the specification may not introduce new matter into the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Claims 2-15, 19 and 20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

- a) Claim 20 is vague and indefinite in that the moieties in the definition of X_1 , X_2 , X_3 , X_4 are not stated as a Markush group. X_1 , X_2 , X_3 and X_4 are **or** or X_1 , X_2 , X_3 and X_4 are selected from the group consisting of **and** is suggested.
- b) Claim 20 is vague and indefinite in that the moieties in the definition of R are not stated as a Markush group. R is..... **or** or R is selected from the group consisting of **and** is suggested.
- c) Claim 20 is vague and indefinite in that the moieties in the definition of r are not stated as a Markush group. Both occurrences of the variable r is..... **or** or r is selected from the group consisting of **and** is suggested.
- d) Claim 20 is vague and indefinite in that it is not known what is meant by “ R_3 is selected from the group consisting of” when there is only one moiety listed.
- e) Claim 20 is vague and indefinite in that the definition of R_3 includes a moiety which fails to indicate the point of attachment.
- f) Claim 20 is vague and indefinite in that it is not known what is meant by “naphtalene” in the definition of Ar_1 .

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- g) Claims 2, 3, 12-15, 19 and 20 are vague and indefinite in that the moiety (CH₂)_g-R₁₀ in the definition of R₉ is missing the point of attachment and the 2 and g are not represented by subscripts.
- h) Claims 2, 3, 6, 12-15, 19 and 20 are vague and indefinite in that the moieties in the definition of g are not stated as a Markush group. The variable g is..... **or** or g is selected from the group consisting of **and** is suggested.
- i) Claims 2, 3, 6, 12-15, 19 and 20 are vague and indefinite in that the moieties in the definition of R₁₀ are not stated as a Markush group. R₁₀ is..... **or** or R₁₀ is selected from the group consisting of **and** is suggested.
- j) Claims 2, 3, 12-15, 19 and 20 are vague and indefinite in that it is not known what is meant by the moiety where R₈ and R₉ together with the N atom to which they are linked form a piperazine, optionally substituted on **one** of its nitrogens by a C₁₋₃ alkyl, C₁₋₃ acyl or methanesulfonyl.
- k) Claims 2, 3, 12-15, 19 and 20 are vague and indefinite in that the moieties in the definition of R₁₁ are not stated as a Markush group. R₁₁ is..... **or** or R₁₁ is selected from the group consisting of **and** is suggested.
- l) Claims 2, 3, 12-15, 19 and 20 are vague and indefinite in that the moieties in the definition of h are not stated as a Markush group. The variable h is..... **or** or h is selected from the group consisting of **and** is suggested.

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- m) Claims 2, 3, 12-15, 19 and 20 are vague and indefinite in that it is not known what is meant by “an hydroxy” in the definition of R_{12} , both occurrences.
- n) Claims 2, 3, 12-15, 19 and 20 are vague and indefinite in that it is not known what is meant by “hydroxy carboxyamido” in the definition of R_{12} .
- o) Claims 2, 3, 12-15, 19 and 20 are vague and indefinite in that the moieties in the definition of R_4 are not stated as a Markush group. R_4 is..... **or** or R_4 is selected from the group consisting of **and** is suggested.
- p) Claims 2, 3, 12-15, 19 and 20 are vague and indefinite in that it is not known what is meant by a C_{2-6} alkyl containing one or more **ether** or hydroxy groups in the definition of R_{13} .
- q) Claims 2, 3, 12-15, 19 and 20 are vague and indefinite in that it is not known what is meant by “as enantiomers or mixture of diastereoisomers”.
- r) Claim 2 is vague and indefinite in that the definition of X_1 , X_2 , X_3 and X_4 includes a moiety which fails to indicate the point of attachment.
- s) Claim 2 is vague and indefinite in that it is not known what is meant by the definition of R_1 and R_2 which “are the same or different, are”.
- t) Claim 2 is vague and indefinite in that it is not known what is meant by the phrase “two residues with substituents” in the definition of Ar.

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- u) Claim 2 is vague and indefinite in that the substituents of Ar₁ in the definition of Ar₁ are not stated as a Markush group. Substituted with up to two residues selected from the group consisting of **and** is suggested.
- v) Claim 3 is vague and indefinite in that it is not known what is meant by the point of attachment on the X₁, R₁, R₂ and R₃ variables.
- w) Claim 3 is vague and indefinite in that it is not known what is meant by “the lateral chain” of tryptophan and phenylalanine in the definitions of R₁ and R₂, respectively.
- x) Claim 3 is vague and indefinite in that it is not known what is meant by the definition of R₂ which includes the moiety CN 3-pyridyl-methyl.
- y) Claim 3 recites the limitation "3-pyridyl-methyl and 4-pyridyl-methyl" in the definition of the substituents on the phenylalanine moiety. There is insufficient antecedent basis for this limitation in the claim.
- z) Claim 3 is vague and indefinite in that an “and” does not appear before the last definition.
- aa) Claim 4 is vague and indefinite in that it is not known what is meant by the moiety N-~~metan~~sulfonyl-4-piperidinyl in the definition of R₉.
- ab) Claim 4 is vague and indefinite in that it is not known what is meant by the moiety N-methyl-4-piperaziniyl in the definition of R₈ and R₉ together.

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- ac) Claim 4 is vague and indefinite in that the moieties in the definition of R_8 and R_9 together are not stated as a Markush group. R_8 and R_9 together are **or** is suggested.
- ad) Claims 4, 5, 7, 9 and 11 do not end with a period indicating the end of the claim.
- ae) Claims 5, 7, 9 and 11 recite the limitation "-NHCO-" in the definition of X_3 for each of the species. There is insufficient antecedent basis for this limitation in the claim.
- af) Claim 5 recites the limitation "Ala(4-pyridyl)" in the xiii species. There is insufficient antecedent basis for this limitation in the claim.
- ag) Claim 5 recites the limitation "Ala(3-pyridyl)" in the xiv species. There is insufficient antecedent basis for this limitation in the claim.
- ah) Claim 5 is vague and indefinite in that the xiii and xiv species are both missing an open parenthesis.
- ai) Claims 5, 7, 9 and 11 are vague and indefinite in that the list of species are not stated as a Markush group. It is believed that an "or" should appear before the last species.
- aj) Claim 6 is vague and indefinite in that the moieties in the definition of R_9 are not stated as a Markush group. R_9 is..... **or** or R_9 is selected from the group consisting of **and** is suggested.

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- ak) Claim 6 is vague and indefinite in that the moiety $(CH_2)_g-R_{10}$ in the definition of R_9 is missing the point of attachment and the g is not represented by a subscript.
- al) Claim 7 is vague and indefinite in that it is not known what is meant by 4-methanesulfonylamino in the xxi and xxii species.
- am) Claim 7 is vague and indefinite in that it is not known what is meant by the xxviii species which has "AMENDED SHEET" running through the nomenclature of the species.
- an) Claim 8 recites the limitation "4-hydroxypiperidine, 4-carboxyamido-piperidine, 4-aminosulfonylpiperazine and 4-hydroxy-cyclohexan-1-yl-amino" in the definition of R_{12} . There is insufficient antecedent basis for this limitation in the claim.
- ao) Claim 8 is vague and indefinite in that the moieties in the definition of R_{12} are not stated as a Markush group. R_{12} is..... **or** or R_{12} is selected from the group consisting of **and** is suggested.
- ap) Claim 9 is vague and indefinite in that it is not known what is meant by furanil in the xxxv species.
- aq) Claim 9 is vague and indefinite in that it is not known what is meant by the xxxix species which has "AMENDED SHEET" running through the nomenclature of the species.
- ar) Claim 9 is vague and indefinite in that the xxxix species is missing a close $\}$ and a close bracket.

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- as) Claim 9 recites the limitation "*trans*-4-hydroxy-cyclohexan-1-yl-amino" in the xlv species. There is insufficient antecedent basis for this limitation in the claim.
- at) Claim 10 recites the limitation "4-(hydroxyethyloxyethyl)-piperazine" in the definition of R₁₃. There is insufficient antecedent basis for this limitation in the claim.
- au) Claim 11 recites the limitation "4-(hydroxyethyloxyethyl)-piperazine" in the xlviii species. There is insufficient antecedent basis for this limitation in the claim.
- av) Claims 13-15 are substantial duplicates of claim 12, as the only difference is a statement of intended use which is not given material weight. Note In re Tuominen 213 USPQ 89.
- aw) Claim 19 is vague and indefinite in that it is dependent on canceled claim 1.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

- 4. Claims 2-5, 12-15, 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over GIORGI et al., WO 98/34949. The generic structure of GIORGI encompasses the instantly claimed compounds (see Formula I, page 1) and for the same use as claimed herein. Examples 1,

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2, 4-19, etc. differ only in the nature of the R_4 substituent. Page 2, lines 4-32 defines the substituent R_4 as hydrogen, C_{1-6} alkyl or -L-Q where L is a chemical bond or a linear or branched C_{1-6} alkyl residue and Q is a group chosen from among i) H, OH, NR_9R_{10} where R_9 and R_{10} , which may be the same or different from one another, represent a hydrogen..... or where R_9R_{10} joined together with the N-atom a saturated 4-6 membered heterocycle possibly containing a further heteroatom chosen in the group consisting of N, O, S.... Compounds of the instant invention are generically embraced by GIORGI in view of the interchange ability of the R_4 substituent of the monocyclic ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example piperazine as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 2-5, 12-15, 19 and 20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 09/355,210. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compounds, compositions and method of use of the instant invention is embraced by the compounds, compositions and method of use of the monocyclic compounds of 09/355,210.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Coleman whose telephone number is (703) 305-1880. The examiner can normally be reached on Mondays and Tuesdays from 9:00 AM to 3:00 PM and from 5:30 PM to 7:30 PM and on Wednesday thru Friday from 9:00 AM to 6:00 PM.

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The fax phone number for this Group is (703) 308-4734 for “unofficial” purposes and the actual number for **OFFICIAL** business is **308-4556**.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

A handwritten signature in black ink that reads "Brenda Coleman". The signature is written in a cursive style with a large, looping "C" at the end.

Brenda Coleman
Primary Examiner AU 1624
May 17, 2002